

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

Q-MED AB,

Plaintiff.

- against -

HA NORTH AMERICAN SALES AB,  
MEDICIS AESTHETICS HOLDINGS INC., and  
MEDICIS PHARMACEUTICAL CORP.,

Defendants.

12 Civ. 8071 (RJS)

**DECLARATION OF DORIS  
DAY, M.D. IN SUPPORT OF  
DEFENDANTS' OPPOSITION  
TO Q-MED AB'S MOTION  
FOR PRELIMINARY  
INJUNCTION**

DORIS DAY, M.D., declares under penalty of perjury, pursuant to 28  
U.S.C. § 1746, as follows:

1. I submit this Declaration in support of Defendants' opposition to  
Q-Med AB ("Q-Med")'s motion for a preliminary injunction.

**Background and Qualifications**

2. I am a board-certified dermatologist who specializes in laser,  
cosmetic and surgical dermatology, licensed to practice medicine in New York and  
California. I am affiliated with Lenox Hill Hospital and New York University Medical  
Center. I am a Clinical Assistant Professor of Dermatology at New York University  
Langone Medical Center.

3. I have a B.A. from Barnard College, an M.A. in Journalism with a  
special certificate in science writing from New York University, and an M.D. from the  
State University of New York Downstate College of Medicine. I completed a

dermatology residency at Cornell University/The New York Hospital, where I was Chief Resident.

4. I am a member of the New York Facial Plastic Surgery Society, the American Society of Dermatologic Surgery, the American Academy of Dermatology, the International Academy for Dental-Facial Esthetics, the Women's Dermatologic Society, the New York State Dermatology Society, and the Skin Cancer Foundation Leadership Society.

5. I have written and spoken extensively on cosmetic dermatology, in both the popular press and in academic settings. I have written two books, entitled *Forget the Facelift*, which discusses the use of dermal fillers, and *100 Questions and Answers About Acne*. I have been associated with documentaries on cosmetic procedures for the Discovery Channel, am a frequent guest expert on *Good Morning America*, and have commented on CNN, Fox News, MSNBC, *The Today Show*, and numerous other television shows. I am regularly quoted in major women's magazines, including *Allure*, *In Style*, *Vogue*, *Glamour*, *W.*, *Redbook* and others. I am also a radio talk show host for the Dermatology Show on Doctor Radio, Sirius XM 81.

6. I have participated in several Advisory Boards and also as a speaker for Medicis Medical as well as Aesthetic, for which I have been compensated. I have had substantially similar relationships with various other pharmaceutical firms over the years. Among them, I previously participated in professional activities for Sanofi-Aventis, the former manufacturer of Sculptra, for which I was compensated. I have also participated in Ad Boards and speaker events for Galderma, for which I was compensated.

7. I understand that Q-Med has asserted in this litigation that Sculptra, a dermal filler product sold by Valeant, is “directly competitive” with Restylane and Perlane, two dermal filler products marketed by Medicis. Based on my experience, Sculptra is not “directly competitive” with either Restylane or Perlane. Sculptra is a volumizing product, whereas Restylane and Perlane are true dermal fillers.

8. I am deeply familiar with each of these products. I frequently use them in my practice. Indeed, I am qualified as a trainer in Sculptra. When Sculptra was first approved by the FDA for use in 2004, I was a frequent early injector of the product, and as such, became qualified to train other physicians as to the technique for injecting the product, and consulted for the distributor of the product (then Sanofi-Aventis) doing so. I was also an observing investigator for the FDA trials of Restylane and was a frequent early user of this product (which I still use frequently). I also lecture regularly to my peers about both and other products. In the last year, for example, I performed approximately 100 Sculptra injections, and approximately 400 Restylane injections.

**Background.**

9. Restylane is a hyaluronic acid (“HA”) dermal filler. HA is a form of molecule that exists naturally in the human body. Restylane is a synthetic hyaluronic acid in gel form that is used, for example, to treat facial wrinkles and folds, as well as lip augmentation. After a period of time, generally about 6-9 months, Restylane is naturally absorbed into the body.

10. Restylane is indicated for, among other areas, the nasolabial folds, the folds that run vertically from nose to mouth. In 2011, the FDA approved Medicis’s PMA supplement to expand the approved use of Restylane to include lip augmentation.

The new label includes an indication for submucosal implantation for lip augmentation in patients over the age of 21. I regularly perform such injections in my practice.

11. Sculptra, by contrast, is made of poly-L-lactic acid as opposed to HA, and is sometimes referred to as a bio-particle filler. It is not typically injected in the dermis; rather, it is used at a deeper layer of the face. Sculptra adds volume to the face in a more global way to reframe the sculpture of the face and the injected particles create a reaction that helps in restoring the body's natural collagen. Where an HA product will fill up wrinkles, Sculptra is more typically used to substantially augment broader areas affected by facial lipoatrophy or loss.

**Sculptra and Restylane Are Complementary, Not Directly Competitive.**

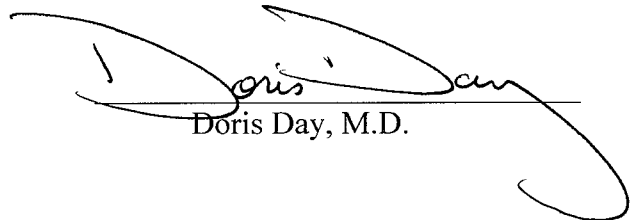
12. I view these two products as very different. Put simply, Sculptra is a volumizing product that restores collagen used where there has been facial lipoatrophy. It does not produce immediate results and several treatment sessions spaced at least 6 weeks apart are required for optimal results. The spacing of the treatments is also important because the results are gradual and there needs to be time between treatments to allow for full effect before more product is added in order to avoid over-volumizing. This is different than with HA where we often aim to correct to 100% at the first visit. Although Sculptra may be indicated for the nasolabial folds, in practice, physicians rarely use it solely in that context. It is more frequently injected along the jaw line, in the cheeks, and temples. It is often my first choice product for temple and mid face lipoatrophy. Additionally, it is not advised to use Sculptra for the lips or periorbital region. I consider the principal competitor to Sculptra to be Radiesse, which is another bio-particle filler product that, like Sculptra, has a volumizing effect.

13. In contrast, Restylane is what I consider to be a dermal filler. It fills wrinkles and creases with immediate results. I typically use it for lip augmentation as well as to address more mild skin wrinkles. It is my first choice product for relatively mild creases around the eyes and mouth, as well as after Sculptra treatments to finesse and add contour in a more discrete and definitive way. This is because Restylane is placed exactly where the volume is desired while Sculptra is injected more broadly to volumize a general region of the face. From my perspective, as a physician, the principal direct competitor to Restylane is the Juvederm family of products.

14. I consider Sculptra and Restylane to be complementary. Patients who receive treatments with Sculptra will, after it takes effect, frequently come back for additional touch-up work using Restylane. I estimate that 80% of my patients who receive Sculptra treatments also receive Restylane injections at some subsequent point, in the same or other areas as where Sculptra has been injected (i.e., lips, periorbital region). In contrast, patients who use Restylane as their primary treatment almost never also get Sculptra treatments. When I lecture to my peers at conferences about the use of injectable fillers, I regularly make the point that superior results are typically obtained when using an HA filler, like Restylane, as a supplement to a bio-particle filler such as Sculptra.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: New York, New York  
November 14, 2012



Doris Day, M.D.